DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 29 2002

Re: Starlix
Docket No.: 01E-0367

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 34,878, filed by Novartis, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Starlix, the human drug product claimed by the patent.

The total length of the regulatory review period for Starlix is 2,147 days. Of this time, 1,775 days occurred during the testing phase and 372 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 7, 1995.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 7, 1995.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: December 17, 1999.

   FDA has verified the applicant's claim that the new drug application (NDA) for Starlix (NDA 21-204) was initially submitted on December 17, 1999.

3. The date the application was approved: December 22, 2000.

   FDA has verified the applicant's claim that NDA 21-204 was approved on December 22, 2000.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Thomas Hoxie
Novartis Pharm.
Patent & Trademark Dept.
564 Morris Ave.
Summit, NJ 07901-1027